

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant	:	William J. Wechter	Group Art Unit Unknown
Appl. No.	:	Unassigned	
Filed	:	Herewith	
For	:	USE OF $\gamma$ -TOCOPHEROL AND ITS OXIDATIVE MATABOLITE LLU- $\alpha$ IN THE TREATMENT OF DISEASE	
Examiner	:	Unknown	

REQUEST BY APPLICANT OF INTERFERENCE PURSUANT TO 37 C.F.R. § 1.604(a)

United States Patent and Trademark Office  
P.O. Box 2327  
Arlington, VA 22202

Dear Sir:

The Applicant herewith submits the above-named application having Claims 1-16, which correspond to or encompass Claims 41-64 of U.S. Patent Application No. 10/017,717 by Miller et al. The present application ultimately claims priority under 35 U.S.C. § 120 to U.S. Application No. 09/215,608, filed December 17, 1998, and contains substantially the same disclosure as that earlier application. Accordingly, the effective filing date of the present application is December 17, 1998, which is well before the earliest claimed priority date of the Miller et al. application.

PROVOCATION OF INTERFERENCE PURSUANT TO 37 C.F.R. § 1.604(a)Identification Of Other Application

Applicant requests that an interference be declared between the present application and U.S. Patent Application No. 10/017,717 by Miller et al. The Miller et al. application was published on September 19, 2002 as Publication No. 2002/0132845 A1. Since the present

application is being filed within one year of this publication date, the requirements of 35 U.S.C. § 135(b)(2) have been met.

Proposed Count

Claims 41-64 in U.S. App. No. 10/017,717 by Miller et al. correspond to the claims of the present application. Accordingly, Applicant proposes that the count be all of the claims of the present application (i.e., Claims 1-16).

Identification Of Claims In Other Application Corresponding To The Proposed Count

Claims 41-64 of U.S. Application No. 10/017,717 by Miller et al. correspond to the proposed count. Although these claims are not identical to the proposed count, as described below, there is no patentable distinction between these claims and the proposed count.

Claims 41, 42, 44-47, 51 and 58-61 in Miller et al. are identical to Claims 1, 2, 4-7, 10 and 12-15 of the present application, respectively.

Claim 43 in Miller et al. is patentably indistinct from Claim 3 of the present application. Claim 43 recites “[a] method for treating and/or ameliorating the symptoms of a non-cardiovascular tissue ischemic condition” selected from a group consisting of various types of ischemia. Likewise, Claim 3 recites “[a] method for treating and/or ameliorating the symptoms of a non-cardiovascular tissue ischemic condition” selected from a group consisting of various types of ischemia, wherein said types of ischemia coincide with several of the types of ischemia recited in Claim 43.

Claims 48-52 in Miller et al. are patentably indistinct from Claims 8 and 9 in the present application. Claims 48-52 recite “[a] method for treating and/or ameliorating the symptoms of a non-cardiovascular tissue ischemic condition,” comprising administering a gamma-tocopherol metabolite enriched tocopherol composition comprising at least 80%, 85%, 90%, 95%, and 98% gamma-tocopherol, respectively. Claims 8 and 9 in the present application recite the same method wherein the gamma-tocopherol enriched tocopherol composition comprises at least 50% to 100%, and 55% to 95% gamma-tocopherol, respectively.

Claims 53-56 in Miller et al. are patentably indistinct from Claim 11 in the present application. Claims 53-56 recite “[a] method for treating and/or ameliorating the symptoms of a non-cardiovascular tissue ischemic condition,” comprising administering a gamma-tocopherol

metabolite enriched composition comprising at least” 80%, 85%, 90%, and 95% gamma-tocopherol metabolite, respectively. Claim 11 in the present application recites the same method, wherein the gamma-tocopherol metabolite enriched composition comprises at least 5% to 95% gamma tocopherol metabolite.

Claims 62-64 in Miller et al. are patentably indistinct from Claim 16 in the present application. Claims 62-64 recite “[a] method for treating and/or ameliorating the symptoms of a non-cardiovascular tissue ischemic condition,” comprising administering a composition comprising gamma-tocopherol in a range of about 1 to about 50 mg/kg, 1 to about 100 mg/kg, and 10 to about 100 mg per kg body weight, respectively. Claim 16 in the present application recites the same method, wherein the composition comprises gamma-tocopherol at 20 mg/kg body weight.

Claim 57 in Miller et al. is patentably indistinct from Claim 2 in the present application. Claim 57 recites “[a] method for treating and/or ameliorating the symptoms of a non-cardiovascular tissue ischemic condition,” comprising administering a gamma-tocopherol metabolite enriched composition comprising at least 98% gamma-tocopherol metabolite. Claim 2 in the present application recites the same method and encompasses a gamma-tocopherol metabolite enriched composition comprising at least 98% gamma-tocopherol metabolite.

#### Explanation Favoring Declaration of Interference

A basis exists for the declaration of an interference between the present application and U.S. Application No. 10/017,717 by Miller et al. As noted above, Claims 1-16 of the present application correspond to Claims 41-64 in the Miller et al. application.

#### Support in Specification for Claims of the Present Application

The specification of the present application provides support for all the claims of the proposed count.

The method recited in Claim 1 is disclosed in page 4, lines 1-3, 20-23 and in page 6, lines 14-16. Claim 1 is also supported by Example 24, which describes the “reduction of platelet binding to adhesive proteins,” and Example 28, which describes the “treatment and prevention of neuropathological lesions.” See page 48, 51. Likewise, the method of Claim 2 is also supported

by page 4, lines 1-3, 20-23 and Examples 24 and 28, as well as by page 5, lines 23-25, page 6, lines 1-18.

The specification discloses “methods of treating and preventing neurological diseases including hyporeflexia, ophthalmoplegia, and axonal dystrophy” in support of Claim 3. See Page 4, lines 24-25; see also page 7, lines 29-31 and page 51, Example 28. The specification also discloses that a “supplement of  $\gamma$ -tocopherol preferably contains at least 60-65%” in support of Claims 4 and 5. See page 8, line 22. Additionally, page 7 discloses that “[p]articularly preferred compositions include at least 70%  $\gamma$ -tocopherol,” in support of Claim 6. See page 8, lines 24-25.

The specification supports Claim 7, disclosing supplying a supplement containing “a formulation of  $\gamma$ -tocopherol 75%.” See page 47, line 17. Page 8 provides support for Claims 8-10, disclosing that “formulations of  $\gamma$ -tocopherol that would be effective for use in the disclosed methods may include as low as 50% (weight to weight)  $\gamma$ -tocopherol or up to 100% (weight to weight)  $\gamma$ -tocopherol, but desirably contain 55% (weight to weight)  $\gamma$ -tocopherol to 95% (weight to weight)  $\gamma$ -tocopherol.” Page 8, lines 26-29.

The specification also discloses that a “supplement comprising  $\gamma$ -tocopherol and a  $\gamma$ -tocopherol derivative preferably contains 5% to 95% (weight to weight)  $\gamma$ -tocopherol mixed with 5% to 95%  $\gamma$ -tocopherol derivative,” which supports Claims 11 and 12. See page 22, lines 16-18. Additionally, the specification discloses that  $\gamma$ -tocopherol “may also be administered with physiologically suitable carriers such as, for example, olive oil, sesame oil, or other lipid,” which also provides support to Claim 12. See page 23, lines 5-7.

The specification identifies as “a further embodiment [of the invention] a medicament comprising  $\gamma$ -tocopherol.” Page 3, line 24. Additionally, “[t]he preparation of soft gelatin capsules comprising commercially available  $\gamma$ -tocopherol,” is disclosed. Page 8, lines 19-20. Accordingly, the specification provides support for Claim 13. The specification further discloses that “[t]he compounds can be administered orally or parenterally,” which provides support for Claims 14 and 15. See page 23, line 7.

Example 28 provides support for Claim 16, disclosing that “[t]he experimental group of vitamin E deficient rats is treated with either 20 mg/kg of  $\gamma$ -tocopherol or a formulation 75% (weight to weight) of  $\gamma$ -tocopherol and 25% (weight to weight) LLU- $\alpha$ .” See page 51.

CONCLUSION

Applicant has fulfilled all the requirements to provoke an interference. Accordingly, examination with special dispatch in accordance with 37 C.F.R. § 1.607(b) is respectfully requested.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 12 Sept 2003

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